OCT 17 2002

Re: K012816

Appendix A (Summary of Safety And Effectiveness)

Submitter:
John Gagliardi, President **(contact person)**
MidWest Process Innovation, LLC
7736 Woodside Court
Maineville, OH 45039
513-573-0085 (Telephone and fax) **or**
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Trade Name: Dynarex Iodoform Packing Strip

Common Name: Iodoform Packing Strip

Classification Name: Unclassified

Iodoform: 5%

Summary of Safety and Effectiveness:
The Dynarex Iodoform Packing Strip is substantially equivalent in function and intended use to these examples of products presently on the market.

Specifically, the Dynarex Iodoform Packing Strip is exactly similar in functional design, performs the same functions and has the same intended use as these presently distributed devices.

The packaging methods and packaging materials are exactly the same, respectively.

The Dynarex Iodoform Packing Strip is a device for general use in wound packing and management and is not different than the predicate device example, therefore the safety, effectiveness and overall function of this device is assured.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Mr. John Gagliardi
President
MidWest Process Innovation, LLC
7736 Woodside Court
Maineville, Ohio 45039

Re: K012816
Trade/Device Name: Dynarex Iodoform Packing Strip
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 19, 2002
Received: August 22, 2002

Dear Mr. Gagliardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012816

Revised: 5/26/02

Device Name: Dynarex Iodoform Packing Strip

Indications for Use: The Dynarex Iodoform Packing Strip is a device used as an anti-bacterial barrier and for general use in wound packing and management. This Iodoform Packing Strip is indicated for external use only. Federal (USA) law restricts this device to sale by or on the order of a physician.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012816